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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,957	03/07/2002	Kenneth M. Yates	CARR-0083 (103216.00251)	7354
25555	7590	02/04/2004	EXAMINER	
JACKSON WALKER LLP 2435 NORTH CENTRAL EXPRESSWAY SUITE 600 RICHARDSON, TX 75080			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/092,957

**Applicant(s)**

YATES ET AL.

**Examiner**

Francisco C Prats

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 6-10 and 13-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**DETAILED ACTION**

Claims 1-63 are pending.

***Election/Restrictions***

Applicant's election without traverse of the group I invention, claims 1-5, 11 and 12 in the paper filed December 8, 2003, (certificate of mailing of December 4, 2003) is acknowledged.

Claims 6-10 and 13-63 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. As noted immediately above, election was made **without** traverse in the paper filed December 8, 2003.

Claims 1-5, 11 and 12 are examined on the merits.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wunderlich et al (U.S. Pat. 5,387,415) in light of McAnalley (U.S. Pat. 4,735,935) (US '935) and McAnalley et al (U.S. Pat. 5,106,616) (US '616).

Wunderlich describes dried pellet compositions prepared from processed and dried Aloe vera juice containing 0.6 weight% solids and collagen hydrolysates having mean molecular weights of 3,000 (Examples 1-3) and 13,000 to 18,000 (Example 4), which is within the claimed molecular weight range. See Examples 1-4, at column 9, line 40 through column 10, line 54. Note that the compositions are disclosed as being readily soluble in water (see, e.g., column 9, lines 60-61) and can be used in juice drinks (see, e.g., column 10, lines 8-10; see also column 9, lines 16-18). Note further that, even if the pellets themselves are not considered tablets, Wunderlich discloses generally that the compositions disclosed therein are suitable for use in tablets and capsules. See column 9, lines 9-15. Thus, Wunderlich discloses a product having the claimed physical form and the claimed ingredients.

Wunderlich also discloses that the ingredients are in the claimed ratios. In Example 1, the final dried composition contains 10.7% aloe vera content. See column 9, lines 57 and 58. Because the only other ingredient present therein is the

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collagen hydrolysate, the collagen is present at 89.3%. Thus, the ratio of plant solid to pharmaceutical auxiliary is 10.7 to 89.3 (about 1:8.35), which clearly falls within the broad ratio of claim 1, as well as the ratio of "about 1:10 to about 1:40" recited in claim 2.

Similarly, in Example 2, the final dried composition contains 5.7% aloe vera content. See column 10, lines 6-8. Because the collagen hydrolysate represents half of the remaining ingredients, i.e. half of 94.3%, the collagen is present at about 47.15%. Thus, the ratio of plant solid to pharmaceutical auxiliary is 5.7 to 47.15 (about 1:8.27), which clearly falls within the broad ratio of claim 1, as well as the ratio of "about 1:10 to about 1:40" recited in claim 2.

In Example 4 part (a), the final dried pellet composition contains 7.4% aloe vera content. See column 10, lines 36-38. Because the only other ingredient present therein is the collagen hydrolysate, the collagen is present at 92.6%. Thus, the ratio of plant solid to pharmaceutical auxiliary is 7.4 to 92.6 (about 1:12.51), which clearly falls within the broad ratio of claim 1, as well as the ratio of "about 1:10 to about 1:40" recited in claim 2. Thus, Wunderlich not only discloses the claimed ingredients in the claimed physical form, Wunderlich discloses the claimed ratios of ingredients.

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Wunderlich's compositions also inherently contain the claimed amounts of water-soluble complex carbohydrates. Specifically, the aloe juice used by Wunderlich inherently contains 338 to 1109 mg/L (i.e. 0.0338 to 0.1109%) of acemannan (see column 12, lines 9-10 of US '616) and approximately 0.05 to 0.3% of "Carrisyn<sup>TM</sup>" (see sentence spanning columns 34 and 35 of US '935). Because the total dry matter in the aloe juice of Wunderlich is 0.6%, and because the complex carbohydrate in the juice ranges from about 0.03% to 0.3%, the percentage of complex carbohydrate vis-à-vis total aloe solids in Wunderlich's compositions ranges from about 5% (0.03 complex carb in aloe juice disclosed by US '616, divided by 0.6 total aloe solids in aloe juice, multiplied by 100%) to about 50% (0.3 complex carb in aloe juice disclosed by US '935, divided by 0.6 total aloe solids in aloe juice, multiplied by 100%).

Clearly, the amount of carbohydrate falls within the "less than about 50 percent" recited in claim 5. Moreover, because the "more than about 50 percent" recited in claim 4 encompasses values which are more than, say 49 percent, and because the 50 percent in Wunderlich's compositions is more than 49 percent, a holding of anticipation over the cited claims is clearly required.

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**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al (U.S. Pat. 5,443,830), in view of Wunderlich et al (U.S. Pat. 5,387,415).

Moore discloses drink mixes, including dried drink mixes which can be formed into powders or tablets, which comprise the claimed aloe polysaccharides. See, e.g., column 9, lines 24-35. Note in particular the disclosure of suitable polymeric "binding agent[s]" such as starch or maltodextrin in forming tabletted drink mixes. Column 9, lines 29-32. Moore differs from the

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claims in not disclosing the use of auxiliary having the claimed molecular weight.

While it is not believed to be the case, even if it is not considered to anticipate the claims under examination, Wunderlich clearly discloses the advantageousness of using polymeric pharmaceutical auxiliaries having the claimed molecular weight in therapeutic aloe-containing drink mixes. In particular, advantages include shelf stability and the ability to avoid the use of undesirable solvating agents (column 2, lines 3-18), as well as suitable physical characteristics such as porosity and mechanical stability (column 4, lines 19-27). Thus, the artisan of ordinary skill, recognizing from Wunderlich the desirable properties imparted to aloe-containing dried drink mixes of polymeric auxiliaries with the claimed molecular, clearly would have been motivated to have used Wunderlich's auxiliaries in Moore's drink mixes. Because the artisan of ordinary skill would have recognized Wunderlich's auxiliaries to have been desirable in Moore's compositions, a holding of obviousness is clearly required.

No claims are allowed.

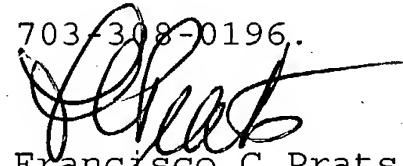


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C. Prats  
Primary Examiner  
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FCP